Detailed Information to the State of the Art in Heart Valve Replacement

The heart beats around 100,000 times a day and 2.5 billion times in a life lasting 70 years. In order to pump the blood in one direction through the body, backwash is avoided by check valves – the heart valves.

Heart valve diseases have several congenital and acquired causes. If there is no treatment, the slowly increasing overload leads to final heart failure. The heart can be relieved either by reconstruction or replacement of the compromised heart valves. Mostly the heart valve defects are so advanced that replacement is required.

The current conventional prosthetic valves have lead to improved quality of life and longer life expectancy for many patients. Heart valve replacement is a clinically established treatment. Out of the four different human heart valves two of them make up 97% of all replaced valves. Two thirds concern the trileaflet aortic valve and one third the bileaflet mitral valve of the left ventricle due to the higher strain.

But there is still no completely satisfactory heart valve substitution. Although the natural aortic and mitral valve construction and function differ essentially from each other, they are
replaced only by one universal type of prosthetic valve, thus disregarding the differences. In spite of great progress in the development of prosthetic valves as well as in postoperative care, all currently available prosthetic valves without exception are afflicted with complications concerning construction or material. 50% of the patients have to undergo reoperation due to complications after 8 to 9 years (biological prostheses) and 11 to 12 years (mechanical prostheses) respectively. (Multicenter study DRURY et al. 1991: 16,000 patients examined in England).

The theoretically unlimited durability of mechanical prostheses is seriously compromised by complications. (see next section). The statistics show that the long-term frequency of reoperation, i.e. after more than 15 years, does not differ significantly from biological prostheses. (DRURY et al. 1991).

**Mechanical heart valve prostheses**

Mechanical heart valve prostheses (bileaflet valve, disc valve, ball valve) are fully artificial technical valve constructions with stiff closing elements. Shape and function do not mirror the natural model. They do fulfill a mechanical valve function, but

- they produce a non-physiological, non-central blood flow with turbulence which may provoke clots at the valve itself and in other organs. That is why patients operated with this type of prosthesis must take anticoagulative drugs for their entire life. In case of accidents this treatment may cause long-lasting bleedings which may be life threatening. In addition, it requires frequent control of blood coagulation parameters to avoid
spontaneous bleedings in case of overdose or clotting and thromboembolism in case of underdose. The fact that blood coagulation parameters are not optimally adjusted is the main reason for complications treated in hospital. Even the prosthesis itself may be compromised with clots at the mobile valve mechanism in spite of anticoagulants. The result may be a disorder of the opening and closing function so that the prosthesis must be changed.

- due to non-physiological blood turbulence and especially high flow velocity and shearing forces at the stiff, narrow closing gaps (cavitation) occurs increased destruction of blood cells (hemolysis) as well as release of coagulation factors.

- they disregard the fundamental differences of the physiological needs in the aortic and the mitral position so they can only be employed universally.

- they produce audible ticking sounds, especially when the valve closes. These sounds vary in loudness according to the type of valve and require the patients to get used to it. Almost half of the patients affected suffer from emotional stress because they do not find any peace from these sounds.

- in spite of theoretically long durability, complications require replacement of the mechanical valve in 50% after 11 to 12 years.

- cannot be employed in patients with a contraindication to anticoagulants.
• in rare cases **material fatigue** in the valve mechanism may lead to sudden fracture of its components.

**Biological heart valve prostheses**

Biological prostheses consist entirely or partially of natural, non-vital tissue (pig heart valves or bovine pericardium) after chemical preservation. Their function with three flexible closing elements is similar to the human aortic valve. Due to the natural shape and near physiological blood flow they dispense with anticoagulation in the aortic position, but

• they **tend to early calcification** in and on the leaflets. The result is hardening (sclerosis) and shrinking. Hardening causes loss of flexibility in the leaflet and thus a progressive narrowing of the valve’s orifice. (valvular stenosis). Shrinking causes incomplete leaflet closing (valvular insufficiency). The younger the patient, the stronger the calcification damage, so biological valves in young patients may lose their function already after 5 years.

• calcification defects usually **limit the durability** to 10 years, in exceptional cases more than 15 years. If a defective tissue valve has to be replaced, then usually at an older age where the chances of surviving such an operation may be lower.

• they are obtained from the trileaflet aortic valve with cylindrical flow pattern and **are not suited as substitutes for** the
completely different bileaflet **mitral valve** with concentric flow pattern.

- they have **higher losses of pressure**, because the leaflet flexibility is reduced due to chemical preservation and the blood flow is slowed down. Therefore, the cardiac valve replacement cannot completely guarantee the desired relief.

**Homografts**

Homografts are human, mostly aortic valves either cryopreserved and treated with antibiotics or freshly transplanted. They fulfill a normal function, but

- they are obtained from the trileaflet aortic valve with cylindrical flow pattern and **are not suited as substitutes for** the completely different bileaflet **mitral valve** with concentric flow pattern.

- due to lack of donors the **availability is limited** and they are not always suitable in size. In addition, storage is complicated.

- in rare cases **severe immunological reactions** may occur requiring immunosuppressive drugs. If these drugs are not tolerated or do not work, the graft may be rejected and another operation is necessary.
The new generation of ADIAM biomechanical heart valve prostheses

The specific ADIAM heart valve prostheses combine all the advantages of both biological and mechanical valves and exclude their disadvantages. For a long time, heart surgeons and especially the patients affected have hoped for this progress. The advantages are the following:

- for the first time, prosthetic valves developed specifically for the aortic and mitral position which correspond to almost physiological flow patterns.

- no lifelong anticoagulative drugs.

- physiological flow pattern with very low losses of energy and pressure for better relief of the strained heart muscle in aortic as well as in mitral position.

- no destruction of blood cells.

- high resistance and safe durability by new ADIAMat high performance polymers and extremely complex processing and production procedures.

- excellent and rapid healing in the perivalvular connective tissue.

- blood and tissue compatibility with no evidence of inflammatory foreign body reaction.
• no emotional stress caused by disturbing sounds.

• individual availability in all required sizes, especially the production of very small sizes is possible.

• excellent surgical use.

• lowering the total cost of treatment.

Despite severe heart valve diseases, a significantly higher life quality and life expectancy is possible as a result of the innovative technologies of be innovative.